UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	**MDL No. 2875** **HON. ROBERT B. KUGLER** **CIVIL NO. 19-2875 (RBK)**
THIS DOCUMENT RELATES TO ALL CASES	

PLAINTIFFS' BRIEF IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT ON FRAUD AGAINST ZHP

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rule

PRELIMINARY STATEMENT

ZHP's sale of valsartan API and finished dose constituted knowing fraud beginning at least as early as July 27, 2017. That was the day ZHP scientist Jinsheng Lin, Ph.D., sent the smoking gun email (which was never provided to or disclosed to the FDA) proving that ZHP knew that its valsartan was contaminated with NDMA, as well as the root cause of its creation. This was more than ten months before ZHP first acknowledged the valsartan nitrosamine contamination. The July 27, 2017 email was sent to multiple people with significant roles at ZHP, including but not limited to Min Li (Vice President of Analytical Operations), Jucai Ge (Quality Assurance Director, API Division), Peng Dong (Deputy Director of Product Technical Affairs), Linda Lin (Director of Regulatory Affairs). (ZHP SOMF ¶ 40-42).[1,2]

That Dr. Lin authored the email identifying nitrosamine impurities makes sense because Dr. Lin worked in CEMAT, a division of ZHP devoted to research into drug impurities. Dr. Lin was in charge of the "lab for process and degradation

[1] For ease of reference, Plaintiffs have filed three statements of undisputed material facts focused on the ZHP, Teva, and Torrent Defendants, respectively. However, each statement includes facts for all three Defendants, so this manner of filing does not constitute a limitation of each statement to its nominal defendant. The Statements of Undisputed Material Facts are cited as "ZHP SOMF," "TEVA SOMF," and "Torrent SOMF."

[2] Plaintiffs also rely on the law and facts discussed in their Brief in Support of Partial Summary Judgment on Express Warranty and Consumer Protection Laws.

impurity research," which was responsible, "to systematically design and conduct forced degradation research on drugs to research the mechanism of process impurity formation, to study the degradation pathway of the degradation impurities…" (ZHP SOMF ¶ 35-39). Min Li explained the role of CEMAT: The "Mission of CEMAT…To solve the most challenging technical problems encountered from research and development to scale up and manufacture of drug substances and finished products, particularly those related to process impurities, degradation products, and solid state and polymorphism." Dr. Li confirmed that "Process impurities would include, for example, the NDMA created by the zinc chloride process…And the creation of NDMA and NDEA in the TEA process with sodium nitrite quenching…" In other words, "CEMAT conducted quality research including analytical methods for identification of impurities." (ZHP SOMF ¶ 35-39).

Dr. Lin's email discussed an impurity that had been identified in a research formulation of irbesartan and unequivocally stated that this impurity was **similar to the NDMA in ZHP's valsartan, and that it resulted from sodium nitrite quenching of sodium azide and there was a need to improve the quenching process (the root cause ultimately admitted by ZHP), and presented a significant cGMP problem**. The conclusion included a warning to the recipients, referred to as "leaders," to address this problem. Min Li confirmed what the email said, including:

> Through the secondary mass spectrometry analysis, it can be inferred that the extra NO substituent is in the cyclic compound fragment, and it is very likely that it is an N-NO compound; **it is similar to the N-nitrosodimethylamine that occurs in valsartan when quenched with sodium nitrite, and its structure is very toxic.**
>
> * * *
>
> **If it is confirmed as the above speculated structure, then its toxicity will be very strong, and there will be an extremely high GMP risk**. **This is a common problem in the production and synthesis of sartan APIs**. **It is recommended** to improve other quenching processes (such as NaClO) along with **the optimization of the valsartan sodium azide quenching process.**

(ZHP SOMF ¶ 40-42).[3]

David Chesney, ZHP's cGMP expert for class certification. testified that, "as a matter of GMP the information in this e-mail needed to be aggressively evaluated by the so-called, quote-unquote, leaders as soon as it was brought to their attention. (ZHP SOMF ¶ 117). Instead, ZHP continued to sell the contaminated, adulterated valsartan and falsely represent that it was the FDA approved, compendial compliant valsartan, manufactured in compliance with cGMPs.

[3] [redacted]

Thus, ZHP was aware of the nitrosamine contamination of its valsartan at least as of July 27, 2017 (but likely earlier), and nevertheless knowingly continued to sell both the API and finished dose forms of its contaminated valsartan as the FDA approved formulation. That is fraud.

ZHP IS LIABLE FOR FRAUD AS A MATTER OF LAW

The fraud subclass includes New Jersey, which is representative of the laws of the other states in the subclass. The five elements of common-law fraud are: (1) a material misrepresentation of a presently existing or past fact; (2) knowledge or belief by the defendant of its falsity; (3) an intention that the other person rely on it; (4) reasonable reliance thereon by the other person; and (5) resulting damages. *Gennari v. Weichert Co. Realtors*, 148 N.J. 582, 610, 691 A.2d 350, 367 (1997) (citing *Jewish Ctr. of Sussex County v. Whale*, 86 N.J. 619, 624-25, 432 A.2d 521 (1981)).[4]

[4] The law is consistent in the states in Fraud subclass group C, See: **AK:** *Cornelison v. TIG Ins.,* 376 P.3d 1255, 1270 (Alaska 2016); **AR:** *Muccio v. Hunt*, 2016 Ark. 178, 4–5, 490 S.W.3d 310, 312–13 (2016); **CO:** *Bristol Bay Prods., LLC v. Lampack,* 2013 CO 60, ¶ 26, 312 P.3d 1155, 1160 (Co. 2013); **DC:** *Saucier v. Countrywide Home Loans*, 64 A.3d 428, 438–39 (D.C. 2013); **FL:** *Townsend v. Morton*, 36 So. 3d 865, 868 (Fla. Dist. Ct. App. 2010); **ID:** *Budget Truck Sales, LLC v. Tilley*, 163 Idaho 841, 847, 419 P.3d 1139, 1145 (2018); **IA**: *Lumley v. Advanced Data-Comm, Inc.,* 773 N.W.2d 562 (Iowa Ct. App. 2009); **LA:** *Albe v. City of New Orleans,* 2014-0186 (La. App. 4 Cir. 9/17/14), 150 So. 3d 361, 368, n.8, *writ denied*, 2014-2166 (La. 12/8/14), 153 So. 3d 445; **MA:** *Balles v. Babcock Power Inc.,* 476 Mass. 565, 573–74, 70 N.E.3d 905, 913 (2017) **MN:** *U.S. Bank N.A. v. Cold Spring Granite Co.,* 802 N.W.2d 363, 373 (Minn. 2011); **NJ:** *SL Indus., Inc. v. Am. Motorists Ins. Co.*, 128 N.J. 188, 208, 607 A.2d 1266, 1277 (1992); **NY:** *Morrow v.*

First, ZHP represented that its API and finished dose containing that API was the FDA approved formulation, compliant with the compendial requirements. (ZHP SOMF ¶145-154, 167). ZHP sold its valsartan API designated as "Valsartan USDMF Grade API" which meant that it complied with what ZHP "submitted with the US FDA under our DMF." (ZHP SOMF ¶ 146.5). The DMF represented that the valsartan was as approved by the FDA, with no quality issues, and contained no "high potency genotoxic" impurities. (ZHP SOMF ¶ 126-134). The quality agreements with Teva and Torrent represented that the manufacturing process would comply with cGMPs, and all FDA regulatory standards and guidance documents would be complied with. (ZHP SOMF ¶ 154.5).

ZHP's representations were false. The valsartan was contaminated with NDMA and NDEA, genotoxic probable human carcinogens, and in the words of

---

MetLife Invs. Ins. Co., 177 A.D.3d 1288, 1289, 113 N.Y.S.3d 421, 423 (2019); **NC:** *Rowan Cty. Bd. of Educ. v. U.S. Gypsum Co.,* 332 N.C. 1, 17, 418 S.E.2d 648, 658–59 (1992)**;** **ND:** *Diemert v. Johnson,* 299 N.W.2d 546, 548 (N.D. 1980) (no materiality component); **OH:** *Siegel v. Ringer,* 2017-Ohio-6969, ¶ 32, 94 N.E.3d 1178, 1185 (Oh. App. 2017); **OK**: *Key Fin., Inc. v. Koon*, 2016 OK CIV APP 27, ¶ 13, 371 P.3d 1133, 1137–38 (Ok. App. 2016); **PR:** *Microsoft Corp. v. Computer Warehouse*, 83 F. Supp. 2d 256, 262 (D.P.R. 2000) (no materiality requirement) **RI:** *McNulty v. Chip,* 116 A.3d 173, 182–83 (R.I. 2015) (no materiality requirement); **SD:** *Stabler v. First State Bank of Roscoe*, 2015 S.D. 44, ¶ 19, 865 N.W.2d 466, 477 (S.D. 2015) (no materiality requirement); **VT:** *Felis v. Downs Rachlin Martin PLLC,* 2015 VT 129, ¶ 13, 200 Vt. 465, 472, 133 A.3d 836, 842 (2015); **VA:** *Corish v. Northcutt,* 87 Va. Cir. 20 (2014); **WA:** *Adams v. King Cty.,* 164 Wash. 2d 640, 662, 192 P.3d 891, 902 (2008); **WY:** *Singer v. Lajaunie,* 2014 WY 159, ¶ 26, 339 P.3d 277, 285 (Wyo. 2014) (no materiality requirement).

ZHP this created, "an unacceptable carcinogenic risk to the intended patient population." (ZHP SOMF ¶ 26-34, 135-143). This rendered the valsartan adulterated (ZHP SOMF ¶ 47-48, 54). These genotoxic carcinogens are so toxic that it would be unethical to deliberately study their effects on humans, or to sell the valsartan knowing of the NDMA contamination. (ZHP SOMF ¶ 139, 163.1). Thus, ZHP made repeated material misrepresentations of a presently existing fact beginning at least as of July 27, 2017, and probably earlier since the email does not suggest that the presence of NDMA in the valsartan was a new finding. Jie Wang admitted ZHP was required "to notify its customers of its knowledge about the NDMA in the valsartan per the July 27, 2017 email." (ZHP SOMF ¶ 163.2).

Second, ZHP knew that its representations that its API and finished dose containing that API was the FDA approved formulation, compliant with the compendial requirements, and manufactured per cGMPs were false. The words in the July 27, 2017 email are clear, confirmed by ZHP's corporate representatives and ZHP's translation of the email provided for depositions, and there is no room for interpretation. (ZHP SOMF ¶ 40-42). The email actually correctly describes the root cause (sodium nitrite quenching of sodium azide) and the need to optimize the sodium azide quenching part of the process. The email also points out that it was known to be a common problem with the manufacture of sartans (ZHP's irbesartan has been confirmed to contain NDEA due to the sodium nitrite quenching, (ZHP

SOMF ¶ 40.5), that it is extremely toxic, and is a serious cGMP problem..[5] This was all true, but was not disclosed.

Third, there was clearly an intent to have others rely on the misrepresentation. This is what allowed the valsartan to be sold, by definition. In fact, Jun Du told the FDA investigator who conducted the inspection following the disclosure of the contamination that the cost savings and increased yield achieved with the manufacturing process change to the zinc chloride process is what **allowed ZHP to dominate the world market for valsartan**. (ZHP SOMF ¶ 20).

Fourth, reasonable reliance cannot be disputed. No TPP would have been able to pay for the contaminated valsartan if the truth had been told because it would not have been sold. (ZHP SOMF ¶ 144, 155-163). Min Li agreed that if ZHP

[5] The text of the email has been confirmed by ZHP at least three times, including by corporate representative Min Li, then Vice Chairman of the Board of Directors of ZHP Jun Du, and ZHP's own translation of the email (ZHP SOMF ¶ 40-42) – any effort to mischaracterize the email should be rejected "The party opposing summary judgment may not "rest upon mere allegation[s] or denials of his pleading," but must set forth specific facts and present affirmative evidence demonstrating that there is a genuine issue for trial. *Id.* at 256-57, 106 S.Ct. 2505; FED. R. CIV. P. 56(c)(1)(A). Additionally, "if the non-moving party's evidence 'is merely colorable, ... or is not significantly probative, ... summary judgment may be granted.' " *Trap Rock Indus., Inc. v. Local 825, Int'l Union of Operating Engineers, AFL-CIO,* 982 F.2d 884, 890-91 (3d Cir. 1992) (quoting *Gray v. York Newspapers, Inc.,* 957 F.2d 1070, 1078 (3d Cir. 1992))." *See also Kuhar v. Petzl Co.,* No. CV 16-0395 (RMB/JS), 2019 WL 5654976, at *3 (D.N.J. Oct. 15, 2019), *report and recommendation adopted*, No. CV 16-395 (RMB/JS), 2019 WL 5622533 (D.N.J. Oct. 31, 2019), *aff'd*, No. 19-3900, 2022 WL 1101580 (3d Cir. Apr. 13, 2022) (same).

"knowingly" sold the valsartan with the documented levels of contamination, that was unacceptable and unethical. (ZHP SOMF ¶ 163.5). [redacted] (ZHP SOMF ¶ 143.5). [redacted] (ZHP SOMF ¶ 163). Just as happened in 2018 when the contamination was finally acknowledged, ZHP would have had to immediately cease sales and recall the contaminated product it had already distributed.

Fifth, Plaintiffs were certainly damaged by paying for adulterated, contaminated valsartan, as if it was the FDA approved formulation – which would not have happened if the truth was told. The only question to be answered at trial is the calculation of the compensatory damages, as well as whether and in what amount punitive damages should be awarded.

CONCLUSION

For the foregoing reasons, Plaintiffs request entry of an Order granting partial summary judgment against ZHP for fraud, saving only the amount of the compensatory damages, as well as whether punitive damages should be awarded, and the amount of punitive damages, as issues to be determined at trial.

Dated: December 22, 2023

Respectfully submitted,

/s/ Ruben Honik
Ruben Honik
HONIK LLC
1515 Market Street, Suite 1100
Philadelphia, PA 19102
Phone: (267) 435-1300
ruben@honiklaw.com

/s/ Daniel Nigh
Daniel Nigh
LEVIN, PAPANTONIO, THOMAS, MITCHELL RAFFERTY & PROCTOR, P.A.
316 South Baylen Street
Pensacola, FL 32502
Phone: (850) 435-7013
dnigh@levinlaw.com

/s/ Adam Slater
Adam Slater
MAZIE, SLATER, KATZ & FREEMAN, LLC
103 Eisenhower Pkwy, 2nd Flr.
Roseland, NJ 07068
Phone: (973) 228-9898
aslater@mazieslater.com

/s/ Conlee S. Whiteley
Conlee S. Whiteley
KANNER & WHITELEY, LLC
701 Camp Street
New Orleans, LA 70130
Phone: (504)-524-5777
c.whiteley@kanner-law.com

MDL Plaintiffs' Co-Lead Counsel

/s/ *Jorge Mestre*
Jorge Mestre
RIVERO MESTRE LLP
2525 Ponce de Leon Blvd., Suite 1000
Miami, FL 33134
Phone (305) 445-2500
jmestre@riveromestre.com

/s/ *Gregory P. Hansel*
Gregory P. Hansel
PRETI, FLAHERTY, BELIVEAU & PACHIOS, CHARTERED, LLP
One City Center
P.O. Box 9546
Portland, ME 04112
Phone: (207) 791-3000
ghansel@preti.com

Third-Party Payor Economic Loss Co-Lead Class Counsel